MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

August 23, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

Subject: Docket No. 99N-1737 – Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions; Request for Comments

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon the above-referenced notice published June 22 by the FDA's Center for Devices and Radiological Health (CDRH).

MDMA, based in Washington, D.C., is the national association for the innovators and entrepreneurs in the medical device industry. Representing 130 independent manufacturers of medical devices, diagnostic products, and health care information systems, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products in the marketplace.

Section 113(b) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) directs the National Institutes of Health (NIH) and the FDA to examine the feasibility of including medical device investigations within the scope of the NIH's public database of information on clinical trials of drugs for serious or life-threatening diseases and conditions. In response, the FDA has invited public comment on whether such a public database of clinical trials of medical devices is in the best interests of the public health.

MDMA Position

MDMA does not believe the establishment of a general public database of clinical trials of medical devices is in the best interests of the public health. Moreover, we believe the existence of such a general public database would be detrimental to the public health by chilling the process of continuous, incremental innovation that is the hallmark of the medical device industry. However, MDMA recognizes that patients may be frustrated by the lack of a central repository of information about clinical trials that have been disclosed by companies. To respond to this concern, MDMA believes the FDA should consider establishing or supporting a central Internet clearinghouse of clinical-trial information volunteered by manufacturers.

99N-1737

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Rationale

The mere existence of a clinical trial of an investigational device is sensitive, proprietary information for the company sponsoring the trial. The FDA currently recognizes this sensitivity by not disclosing the existence of investigational device exemption (IDE) applications except under certain limited circumstances.

MDMA believes that this policy is still appropriate, particularly since entrepreneurial companies with limited resources continue to set the pace of innovation in most sectors of the medical device industry. If forced to disclose the nature and thrust of their research and development efforts, small and entrepreneurial companies may choose not to investigate (at least in the United States) the potential of innovative ideas in fear that other companies will begin their own investigations along the same or similar lines. Unlike drugs, medical devices have effective product lives that, in many cases, are measured by the months, rather than years, before the next incremental advances are brought to market. MDMA believes that, without the possibility of being "first to market" with innovative devices, entrepreneurs would find much less incentive to innovate.

Furthermore, MDMA believes that the investment community could inadvertently harm innovators by misinterpreting the specifics of device trials listed in a public database. Most public medical-technology firms have very small market capitalizations and are extremely vulnerable to the exigencies and vicissitudes of the equity markets. One equity analyst's public misinterpretation of public information can send a small public company's stock into a tailspin that saps the resources it needs to bring its technology to market. Surely, the untimely demise of a small public (or private) company with a promising medical technology is not in the best interests of the public health.

MDMA does not believe that the existence of a public database of device investigations would lead to improper promotion or commercialization of clinical trials or undue pressure to expand the number of patients or sites involved in a particular clinical trial. Despite the potential for recovering some research and development costs, most device manufacturers cannot afford to stage huge, multi-center clinical trials. Instead, one of the main challenges for device manufacturers is to find a handful of capable physicians and medical institutions to serve as investigators and sites.

As a result, clinical trials of medical devices are usually smaller than trials of pharmaceuticals, which depend much less on the physical skills and specific training of the health professionals involved in the trial. To protect both the company and the patients it hopes to serve, device manufacturers clearly would prefer to gather promising safety-and-effectiveness data through limited clinical trials before adding scores of new subjects to their trials.

In sum, MDMA believes the establishment of a public database of clinical trials of medical devices is not in the best interests of the public health. The public disclosure of proprietary information about device investigations would be a major disincentive to the process of medical device innovation. However, MDMA recognizes that patients seeking information on clinical trials are undoubtedly frustrated by the absence of a central repository of information on clinical trials that have been acknowledged or disclosed by sponsors. MDMA recommends that the FDA consider establishing or supporting a central Internet clearinghouse of clinical-trial information volunteered by manufacturers, including links to manufacturers' Web sites. However, MDMA cannot reiterate strongly enough that inclusion of a clinical trial in this or any other database should be voluntary and at the discretion of the sponsor.

Thank you for the opportunity to comment on this important subject.

Very sincerely yours,

Stephen J. Northrup
Executive Director

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